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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,635	KENYON ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *34-45,47-49,54-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33,46 and 50-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 May 2005* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0505,0905,0406,0507*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-59 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 10/19/07 is acknowledged. The traversal is on the ground(s) that the inventions of all groups are related, and would not be burdensome to prosecute them together. This is not found persuasive because the inventions of Groups I-VI lack unity of the invention for reasons set forth of the record mailed on 6/21/07. Each group has its own special technical feature that is not shared by other groups. As such, a search of the inventions in Groups I-VI in a single application would have been burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 34-45, 47-49 and 54-59 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-33, 46, 50-53 are currently under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/25/06, 5/26/05, 5/14/07 and 9/12/05 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Specification

The disclosure is objected to because of the following informalities: Tables 2-8 does not have a title or description such that the information provided in the tables are not clear.

Appropriate correction is required.

Claim Objections

Since Applicants elected T22G5.2 for examination, claims 1-33, 46 and 50-53 are objected to because of they contain non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33, 46, 50-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the

claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The claims recite a polypeptide encoded by a nucleic acid that hybridizes under stringent condition to T22G5.2 clone, or a mammalian homolog or ortholog thereof. The claimed genus of polypeptide encompasses a large number of polypeptide with various sizes and function because nucleic acid hybridizes to T22G5.2 clone only need to share some sequence homology with T22G.2, and such nucleic acid may encode polypeptide of different function than lbp-7 (encoded by T22G5.2). The specification does not describe the function of lbp-7 that is related to screening a compound that modulates aging because there is no description of the nucleic acid in Table 3. The specification also fails to describe any mammalian homolog or ortholog of lbp-7 that has this function. Moreover, the specification does not describe any polypeptide encoded by a nucleic acid that hybridize under stringent condition to T22G5.2 has this function. A search of the prior art reveals that T22G5.2 is expressed at a lower level in daf-/- mutants. However, this does not remedy the deficiency of the instant specification for fail to provide sufficient description for the claimed genus of polypeptide that are used to identify a compound that modulates aging. The specification thus fails to describe the claimed genus by a representative number of species by their complete structure, nor other identifying characteristics. Therefore, the written description requirement is not met.

Claims 1-33, 46, 50-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

The nature of the invention

The nature of the invention is a method for identifying a compound that modulate aging by contacting a test compound with a polypeptide encoded by a nucleic acid that hybridizes under stringent condition to the nucleic acid of T22G5.2, or by the nucleic acid of T22G5.2, or mammalian homolog or ortholog thereof, and determine the functional effect of the compound upon the polypeptide.

The breadth of the claim

The breadth of the claim is very broad. The claimed scope encompasses identifying a compound of any nature by contacting it with a polypeptide encoded by a nucleic acid that hybridizes under stringent condition to T22G5.2 or homolog or ortholog of the T22G5.2, and

determine any type of the functional effect upon the polypeptide. The claimed scope also encompasses identify a compound that is able to modulate aging in any organism.

The teaching of the specification

The teaching of the specification regarding how to identify a compound that modules aging by contacting it to the claimed polypeptide is rather limited. The specification teaches using microarray and other methods to identify genes that changes expression in daf2 or daf16 mutants which prolongs life in C. elegan. The specification discloses class1 and class2 genes which affect the lifespan of C. elegan differently. However, the specification fails to teach what the effect T22G5.2 has in this process is. Although T22G5.2 is listed in Table 3, the specification does not provide an explanation of what roles the genes listed in Table 3 has in the aging process. In other words, the specification fails to explain how to identify a compound that can modulate aging simply by contacting it to the polypeptide encoded by T22G5.2, what type of functional effect is determined that would indicate it is a compound that would modulate aging. The specification also fails to teach what mammalian homologs or orthologs, or polypeptide encoded by a nucleic acid has some homology with T22G5.2 (nucleic acid hybridizes under stringent condition to T22G5.2) would be able to used in the method as claimed. As such, one of skilled in the art would have to rely on the information available in art to practice the method as claimed.

The state of art and level of unpredictability in the art

The state of art at the time of filing is silent with regard to the claimed method. In fact, very little is known about the function of lbp-7, encoded by T22G5.2, with regard to its function in aging. Murphy et al. teach that lbp-7 is a downstream molecule of daf16, whose expression is

down-regulated in daf2- C. elegans, whose life is extended than the wild type. However, Murphy et al. do not provide further teaching on how to identify a compound that modulate aging by contacting said compound with a polypeptide encoded by T22G5.2, a nucleic acid having homology with T22G5.2, or any mammalian homolog or ortholog. The prior art also fails to teach any polypeptide encoded by a nucleic acid hybridizable to the T22G5.2, or a mammalian homolog or ortholog which is related to aging. The prior art also fails to indicate how T22G5.2 is related to aging in organisms other than C. elegan. As such, the nexus between those polypeptide and aging is missing. In view of very limited teaching from the prior art, it does not remedy for the lack of guidance of the specification to enable a skilled artisan to practice the method as claimed. Since the prior art does not teach how to identify a compound that modulates aging by simply contact it with a polypeptide encoded by T22G5.2, a nucleic acid having homology with T22G5.2, or any mammalian homolog or ortholog, and the specification does not teach how to practice the method as claimed, one of skilled in the art would have to engage in undue presentation as claimed. Therefore, the claimed method is not enabled by the instant specification.

Claims 7, 11, 21-33, 51 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 7, the recitation of "wherein the functional effect is determined by measuring enzymatic activity" renders the claim indefinite. It is unclear how to measure an enzymatic activity to determine the functional effect because lbp-7 is not known as an enzyme,

and it is unclear whether its mammalian orthologs or homologs are enzyme. As such, the metes and bounds of the claim cannot be established.

Regarding claim 11, the word "derived" renders the claim indefinite because it is unclear what is the nature and number of the derivative process. In other words, it is unclear what changes one can make to a host cells and still consider it is derived from C. elegant, mouse, rat or human.

Regarding claim 21, the recitation of "contacting a host or host cell expressing the protein and evaluating an age associated parameter" renders the claim indefinite because it is unclear what is used to contact a host or host cell. Claims 22-33 are also rejected for being dependent on claim 21.

Regarding claim 51, the recitation of "the criterion is a preselected value" renders the claim indefinite because it is unclear what preselected value Applicants are referring to. In other words, it is a preselected value of what nature? Is it an actual number or a phenotype?

Regarding claim 52, the recitation of "a preselected statistical significance" renders the claim indefinite because it is unclear what a preselected statistical significance is. In other words, it is unclear how statistical significance may be selected prior to statistical analysis and how such significance can determine a functional effect. Does it mean a statistical significant study point to a functional effect of the compound or not?

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

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PRIMARY EXAMINER